REMARKS

The Office Action mailed January 15, 2004, for the present application has been reviewed. The present amendment makes changes to the sequence listing, specification and claims. Considered together with the following remarks, these changes are believed sufficient to place the application into condition for allowance. No new matter has been added to the application. Applicants express appreciation for thoughtful examination by the Examiner.

The specification has been amended pursuant to 37 C.F.R. § 1.821(d) to incorporate the substitute sequence listing submitted herewith. Amendments to the sequence listing serve only to correct inadvertent mistakes and do not contain new matter.

The amended SEQ ID NO.: 3 is fully disclosed in the application as filed at page 33, line 4 and at page 83, lines 22 through 32.

The amended SEQ ID NO.: 5 is fully disclosed in the application as filed at page 53, lines 32-34 and at page 74, lines 1 through 10. SEQ ID NO.: 5 is a polypeptide sequence that constitutes an internal fragment of SEQ ID NO.: 1, and that is encoded by the nucleic acid sequence identified as SEQ ID NO.: 4. The correct sequence corresponding to SEQ ID NO.: 5 is an inherent property of SEQ ID NO.: 4 and the description provided.

The amended SEQ ID NO.: 6 is fully disclosed in the application as filed at page 35, line 3 and at page 74, lines 11 through 20.

The amended SEQ ID NO.: 7 is fully disclosed in the application as filed at page 33, line 5 and at page 74, lines 22 through 31.

The amended SEQ ID NO.: 13 is fully disclosed in the application as filed, although identified as SEQ ID NO.: 14, at page 56, line 19.

The amended SEQ ID NO.: 14 is fully disclosed in the application as filed, although identified as SEQ ID NO.: 15, at page 56, line 21.

Claims 1-8, 11-12, 19, 21, 34 and 42-56 are currently pending in the application. Upon entry of the amendments herein, claims 1-8, 52-54 and newly added claims 57-63 will be pending and under active consideration. Claims 11, 12, 19, 21, 34, 42-51 and 55-56 are cancelled. Claims 1 and 52 have been amended. Claims 57-63 are newly added.

Claim 1 is amended to better define the term "substantially purified" and to introduce a limitation that claimed OMP-106 polypeptides be "extractable from intact cells at room temperature in 1.25% w/v n-octyl-glucoside." Support for purity terms is found in the specification at page 20, lines 23-37. Support for limitation to polypeptides extractable in n-octyl-glucoside is found throughout the specification, in particular at page 7, lines 16-21 and page 21, lines 1-37. See also, page 9, description of Figure 1; page 11, description of Figure 6; page 12, description of Figure 9A; page 14, lines 19-23; page 16, lines 30-37; page 24, lines 11-18; page 44, lines 28 to page 45, lines 9. Applicants respectfully note this limitation is substantive and not merely an optimization of experimental parameters. Some membrane proteins are extractable in n-octyl-glucoside detergent, as described, while others are not. See e.g., Cain, T.J., et al., *Solubilization of glycosyl-phosphatidylinositol-anchored proteins in quiescent and stimulated neutrophils*, Biochim Biophys Acta. 1235(1):69-78 (1995); Nebl, T., et al, *Proteomic Analysis of a Detergent-resistant Membrane Skeleton from Neutrophil Plasma Membranes*, J. Bio Chem, 227(45): 43399-43409 (2002).

Claims 4 and 7 are amended solely as to form.

Claim 52 is amended to correct an erroneous reference to SEQ ID NO.: 10. Under the amended sequence listing, claim 52 should read on SEQ ID NO.: 9.

Newly added claim 57 recites OMP-106 polypeptides similar to those of claim 1 except that polypeptide structure is defined by amino acid sequence, rather than by apparent molecular weight in an SDS gel. The various claimed sequences are recited in a Markush group. Each member of the claimed Markush group has unity of invention in that it shares common utility and a substantial structural feature with each other member – each sequence is derived from SEQ ID NO.: 9. Search and examination for each member is so closely related that examination of the entire claim may be made without undue burden. Each member of the claimed Markush group is supported in the specification:

A. Incorporates the limitations of cancelled claim 11.

B. Claims sequence "substantially homologous" to SEQ ID NO.: 1 and is supported at page 7, lines 25-26; page 17, lines 16-26; page 18, lines 26-30; page 19, lines 10-14; page 27, lines 22-34; page 53, lines 5-14 and Figure 6.

C. Incorporates the limitations of cancelled claim 34.

D. Claims sequence "substantially homologous" to SEQ ID NO.: 9 and is supported at page 7, lines 25-26; page 17, lines 16-26; page 18, lines 26-30; page 19, lines 10-14; page 27, lines 22-34; page 53, lines 5-14 and Figure 6.

E. Claims SEQ ID NO.: 11, and is supported at page 53, lines 15-23.

F. Claims sequence "substantially homologous" to SEQ ID NO.: 11 and is supported at page 7, lines 25-26; page 17, lines 16-26; page 18, lines 26-30; page 19, lines 10-14; page 27, lines 22-34; page 53, lines 5-14 and Figure 6.

Newly added claim 58 recites fragments of 6 or more continuous amino acid residues of SEQ ID NO.: 1 which fragments are epitopic or immuno-cross reactive with full length polypeptide. These fragments are specifically described at page 24, line 36 through page 25, line

4. Utility is alleged at page 6, lines 3-16. The method of making and using the fragments is set forth at page 19, lines 10-30 and page 24, line 29 through page 25 line 4. Applicants respectfully submit that, at the time of invention, techniques of "epitope mapping" were well known and routinely used by those skilled in the art. See e.g., Corradin, G., *Antigen processing and presentation*, Immunol Lett. 25(1-3):11-13 (1990); Beck-Sickinger, A.G., et al, *Epitope mapping: synthetic approaches to the understanding of molecular recognition in the immune system*, Pharm Acta Helv, 68(1):3-20 (1993); Lane, D.P., et al, *Epitope mapping using bacteriophage peptide libraries*, Curr Opin Immunol., 5(2):268-71 (1993). Applicants further respectfully submit that search and examination for SEQ ID NO.: 1 demonstrates that no epitopic fragments of SEQ ID NO.: 1 exist in the prior art. An STN registry BLAST comparison was made of SEQ ID NO.: 1. To the 35 significant homologies identified, a further limitation was applied to identify homologous sequences which were published or disclosed prior to 1998 as follows: "[Result] and ED < 1998." Exhibit A presents a list of all identified sequences published or disclosed prior to 1998 which have significant homology to SEQ ID NO.: 1. As shown, the only pre-1998 reference with significant homology to SEQ ID NO.: 1 is registry number 184922-39-2. The bibliographic information concerning registry number 184922-39-2 is shown in Exhibit B. As shown, the only pre-1998 reference with significant homology to SEQ ID NO.: 1 is reported by the references of Sasaki et. al., which references have been sworn back in this matter by affidavit pursuant to 37 C.F.R. § 1.131.

Newly added claim 59 recites OMP-106 polypeptides as "product by process" claims in which polypeptide structure is defined by amino acid sequence produced by recombinant expression of a corresponding, encoding nucleic acid sequence. Support for recombinant expression is found throughout the specification, in particular, at page 21, lines 11-14; page 22,

line 31 through page 23 line 2; page 38, line 33 through page 42, line 15. Applicants respectfully note that, as claims to polypeptides, the "product by process" claim 59 falls within Examiner's restriction requirements. Applicants further respectfully note that search and examination is not unduly burdensome, where the same search and examination is required for claim 57. The various claimed sequences are recited in a Markush group. Each member of the claimed Markush group has unity of invention in that it shares common utility and a substantial structural feature with each other member – each sequence is derived from SEQ ID NO.: 9. Search and examination for each member is so closely related that examination of the entire claim may be made without undue burden. Each member of the claimed Markush group is supported in the specification:

A. Incorporates the limitations of cancelled claim 11.

B. Claims sequence "substantially homologous" to SEQ ID NO.: 1 and is supported at page 7, lines 25-26; page 17, lines 16-26; page 18, lines 26-30; page 19, lines 10-14; page 27, lines 22-34; page 53, lines 5-14 and Figure 6.

C. Incorporates the limitations of cancelled claim 34.

D. Claims sequence "substantially homologous" to SEQ ID NO.: 9 and is supported at page 7, lines 25-26; page 17, lines 16-26; pages 18, lines 26-30; page 19, lines 10-14; page 27, lines 22-34; page 53, lines 5-14 and Figure 6.

E. Claims SEQ ID NO.: 11, and is supported at page 53, lines 15-23.

F. Claims sequence "substantially homologous" to SEQ ID NO.: 11 and is supported at page 7, lines 25-26; page 17, lines 16-26; page 18, lines 26-30; page 19, lines 10-14; page 27, lines 22-34; page 53, lines 5-14 and Figure 6.

Newly added claims 60 and 61 recite antigenic compositions comprising any of the claimed OMP-106 polypeptides. The newly added claims incorporate limitations of cancelled claims 21, 44, 45, 50 and 51 and are supported throughout the specification.

Newly added claims 62 and 63 recite immunogenic compositions comprising any of the claimed OMP-106 polypeptides. The newly added claims are supported throughout the specification, in particular, at page 24, line 5 through page 28, line 34.

Applicants submit that all amendments and newly added claims are fully supported by the specification and do not add new matter.

Statutory Double Patenting

Claims 1-8, 11-12, 19, 21, 34 and 42-56 are provisionally rejected for statutory double patenting, pursuant to 35 U.S.C. §101 with respect to claims 1, 3, 4, 6-10,12, 19, 21, 27 and 33-56 of copending application 08/642,712.

Applicants respectfully submit that the objection is obviated in that all claims in copending application 08/642,712 have been cancelled, except claim 27. This sole pending claim recites a method of producing an immune response, which is clearly demarked from any claim to polypeptide compositions pending in this application.

Applicants accordingly respectfully request that this objection be withdrawn.

Non-Statutory Double Patenting

Claims 5, 19, 21 and claims 1-4, 6-8, 11-12, 34 and 42-56 are provisionally rejected for non-statutory "obviousness type" double patenting with respect to pending claims 1, 19, 21 and 27 of copending application No. 08/642,712. Applicants respectfully submit that the objection is

obviated in that all claims in copending application 08/642,712 have been cancelled, except claim 27. This sole pending claim recites a method of producing an immune response, which is clearly demarked from any claim to polypeptide compositions pending in this application.

Applicants further respectfully submit herewith a terminal disclaimer which obviates any possible further objection.

Applicants accordingly respectfully request that this objection be withdrawn.

Lack of Enablement

Claims 19, 42-43, 46-49 and 55-56 are rejected under 35 U.S.C. §112, first paragraph, because the specification does not reasonably enable a vaccine. In response, Applicants have cancelled claims 19, 42-43, 46-49 and 55-56.

Applicants accordingly respectfully request that this objection be withdrawn.

Indefiniteness

Claim 1, and claims dependent thereupon, are rejected as indefinite under 35 U.S.C. §112, second paragraph, for inadequate definition of the term "substantially purified." In response, Applicants have amended claim 1 to recite specific criteria of purity.

Applicants accordingly respectfully request that this objection be withdrawn.

CONCLUSION

In light of the foregoing, Applicants respectfully submit that they have addressed each and every item presented by the Examiner in this Office Action. Favorable reconsideration of all

of the claims as amended is earnestly solicited. Applicants submit that the present application, with new claims 57-63, is in a condition for allowance and respectfully request such allowance.

In the event any further matters requiring attention are noted by Examiner or in the event that prosecution of this application can otherwise be advanced thereby, a telephone call to Applicants' undersigned representative at the number shown below is invited.

Respectfully submitted,

Date: July 14, 2004

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Exhibit A: **List of polypeptide sequences with significant homology to SEQ ID NO.: 1 published or claimed before 1998 as identified by STN/REGISTRY BLAST comparison.**

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68-08-6 OR 296342-84-2 OR 296342-85-3 OR 323218-39-9 OR 323218-41-3 OR
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=> QUE L1 OR (476966-98-0 OR 429075-14-9 OR 518385-09-6 OR 476927-03-4 OR 429059-62-1 OR 487838-34-6 OR 329826-18-8 OR 700750-05-6 OR 488307-36-4 OR 478215-87-1 OR 462444-04-8 OR 462444-03-7 OR 325529-90-6 OR 476141-35-2 OR 700750-03-4 OR 500448-19-1)/RN
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1 487066-97-7/RN

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Exhibit B: Bibliographic information concerning registry number 184922-39-2.

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AN 2001:78537 CAPLUS
DN 134:144470
TI A high molecular weight major outer membrane protein of Moraxella and the
gene encoding it and the diagnosis, prophylaxis and treatment of infection
IN Loosmore, Sheena M.; Sasaki, Ken; Yang, Yan-Ping; Klein, Michel H.
PA Connaught Laboratories Limited, Can.
SO PCT Int. Appl., 247 pp.
CODEN: PIXXD2
DT Patent
LA English
FAN.CNT 1

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	WO 2000-CA870	W	20000726		

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